

SEP 15 1997



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

#15

David L. Rose  
Merck & Co., Inc.  
P.O. Box 2000  
Rahway, NJ 07065-0907

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,199,569

Dear Mr. Rose:

Your letter filed August 18, 1997, noting the necessity of an interim extension, is acknowledged. A copy of your letter will be forwarded to Mr. Wilson so that the Food and Drug Administration's records will be complete.

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,199,569 for a period of one year.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: STROMECTIONOL®

FDA Docket No. 97E-0061

kt

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS**

In re Merck & Co., Inc.  
Request for Patent Term Extension  
U.S. Patent No. 4,199,569

:  
: ORDER GRANTING  
: INTERIM EXTENSION

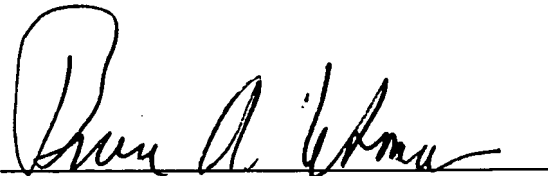
Merck & Co., Inc., the owner of record in the Patent and Trademark Office (PTO) of U.S. Patent No. 4,199,569, filed an application for patent term extension under 35 U.S.C. § 156 on January 8, 1997. The original term of the patent is due to expire on October 3, 1997. The patent claims the active ingredient ivermectin in the human drug product "STROMEKTOL<sup>®</sup>," which was approved by the Food and Drug Administration for commercial marketing or use on November 22, 1996. An extension of 1,026 days is requested.

The initial PTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,199,569 is granted for a period of one year from October 3, 1997, the original expiration date of the patent.

SEP 12 1997

Date



Bruce A. Lehman

Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks